5. 510(K) SUMMARY

510(k) Summary

(per 21 CFR §807.92)

CALLISTO eye™

GENERAL INFORMATION

Manufacturer: Carl Zeiss Meditec AG
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Establishment Registration Number: 9615010

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Date prepared: February 28, 2013

Device: System, Image Management, Ophthalmic
Ocular Marker
Microscope, Surgical

Classification: 21 CFR 892.2050

Device Class: II

Product Code: NFJ HMR EPT

Common Name: Picture Archiving and Communications System
Ophthalmic Surgical Marker
Surgical Microscope and Accessories

Trade/Proprietary Name: CALLISTO eye™

SECTION 5. **510(K) SUMMARY**

PREDICATE DEVICE:

Company: TrueVision Systems, Inc.
Device: TrueVision® 3D Visualization and Guidance System (K101861)

INDICATIONS FOR USE

CALLISTO eye is an assistance system that provides non-diagnostic video documentation and image capture for ophthalmic surgeries. The system allows the remote control of the surgical microscope.

The graphical guidance tools, as displayed on the CALLISTO eye Panel PC or microscope eye piece, aid the surgeon to insert, align, position, and register an artificial lens. These tools are intended for anterior segment ophthalmic surgical procedures, including positioning and angular alignment of toric intraocular lenses, limbal relaxing incisions, and capsulorhexis. The system utilizes surgeon information for positioning of graphical guidance tools.

DEVICE DESCRIPTION

CALLISTO eye is an assistance system that processes real-time video images that can be displayed on the CALLISTO eye panel PC for viewing by the surgeon and the surgical staff in the operating room. The same video images can be viewed by the surgeon through the eyepiece of the OPMI LUMERA 700 surgical microscope. CALLISTO eye provides enhanced visualization and guidance tools to assist the surgeon during procedures such as limbal relaxing incisions, capsulorhexis, and alignment of toric intraocular lenses (IOL). All treatment templates are based on preoperative clinical data of a particular patient and defined by the surgeon prior to the surgery. These templates can be displayed on the CALLISTO eye panel PC and through the eyepiece of the OPMI LUMERA 700 surgical microscope.

CALLISTO eye consists of two product variants: CALLISTO eye BASIC and CALLISTO eye ASSISTANCE.

CALLISTO eye BASIC displays video images and patient data, stores patient data and video recordings, imports and exports patient data and exports videos and images after the surgery. This product variant also allows the remote control of the OPMI LUMERA 700 surgical microscope as well as data injection through the eyepiece via the Integrated Data Injection System (IDIS).

CALLISTO eye ASSISTANCE provides the graphical assistance tools to aid the surgeon during various ophthalmic procedures including limbal relaxing incisions (LRIs), capsulorhexis and toric IOL positioning. The assistance functions include Reference, Rhexis, Incision/LRI, Z-Align and K-track. These functions aid the surgeon in the opening of the capsulorhexis, making incisions and LRIs, aligning the toric intraocular lenses, and

estimating a local corneal curvature during surgery.
For CALLISTO eye BASIC and ASSISTANCE, a database called OR database contains the patient data. The OR database is installed on the integrated PC. Documentation of videos and images can then be stored in this database as standard (SD) or high definition (HD) format.

SUBSTANTIAL EQUIVALENCE

The fundamental technological characteristics of CALLISTO eye with software version 3.0 are similar to the predicate device, TrueVision® 3D Visualization and Guidance System (K101861). Both CALLISTO eye and TrueVision 3D Visualization and Guidance System are devices that work in conjunction with a surgical microscope to assist the surgeon during ophthalmic procedures. Both are used in ophthalmic imaging applications and provide the means for capture, storage, or manipulation of image data and processing of patient information. Both provide the surgical guidance templates and documentation of treatments to aid the surgeon during anterior segment ophthalmic surgical procedures. All templates are set up prior to surgery and can be adjusted during the procedure.

CALLISTO eye and the predicate device consist of:

- a camera connected to a surgical microscope
- a computer providing the imaging application and the means to capture, store or manipulate images and video data as well as the methods for handling patient information
- a flat panel display unit with a resolution of 1920 x 1080 pixels to display HD/SD video content.

All systems provide two dimensional graphical templates, also known as assistance functions, to aid the surgeon during anterior segment ophthalmic surgical procedures, to make an incision, to perform a capsulorhexis, or to position a toric intraocular lens.

One minor difference between CALLISTO eye and predicate device is that the predicate device uses the application of a 3D HD flat panel screen and circular polarized glasses to display live or recorded videos images, whereas CALLISTO eye utilizes a standard 2D HD flat panel to display live or recorded videos and images. Furthermore, CALLISTO eye uses the touch screen as an user interface to omit additional keyboards and pointer devices in the OR setting.

CALLISTO eye and the predicate device serve the same principal purpose of clinical usage and provide a wide range of comparable functionality for their users.

It is the opinion of Carl Zeiss Meditec AG that CALLISTO eye with software version 3.0 is substantially equivalent to the predicate device, TrueVision 3D Visualization and Guidance System (K101861). The indications for use for CALLISTO eye are similar to the indications for use of the predicate device. The technological comparison demonstrates that CALLISTO

eye is functionally equivalent to the predicate device. The minor differences between CALLISTO eye and the predicate device do not raise any new questions of safety or effectiveness in comparison to the predicate device.

PERFORMANCE DATA

Verification and validation testing were completed to demonstrate that the device performance complies with specifications and requirements identified for the CALLISTO eye. A portion of software verification may be considered "bench testing". Each function and/or feature was tested by means of the appropriate test case or test specification. The system verification test report provides the test cases, expected results for each test case and the actual results obtained. All criteria for this testing were met and the results demonstrate that CALLISTO eye meets all performance specifications and requirements. Validation was also conducted for CALLISTO eye according to the Validation Plan to ensure that the device meets the customer's requirements with respect to performance. The objectives defined in the validation plan were achieved according to the validation results.

SUMMARY

As described in this 510(k) Summary, all testing deemed necessary was conducted on CALLISTO eye to ensure that the device is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 5, 2013

Ms. Judith Brimacombe, M.A.
Director, Clinical/Regulatory Affairs
Carl Zeiss Meditec, Inc.
5160 Hacienda Drive
Dublin, CA 94568

Re: K123464
Trade/Device Name: CALLISTO eye™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: NFJ, HMR, EPT
Dated: January 31, 2013
Received: February 1, 2013

Dear Ms. Brimacombe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123464

Device Name: CALLISTO eye™

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Prescription Use___X_____ AND/OR Over-The-Counter Use_____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number:_____K123464_____